2. 510(k) Summary of Safety and Effectiveness Information

Date Prepared:	June 14, 2010
Date Revised:	October 6, 2010
Submitted by:	Merete Medical GmbH Alt Lankwitz 102, 12247 Berlin Germany
Contact Person:	Donna Coleman Merete Medical, Inc. 49 Purchase Street Rye, New York 10580 Phone: 914 967 1532 Fax: 914 967 1542
FDA Registration Number:	3002949614
Proprietary Name:	OsteoBridge® IKA Intramedullary Knee Arthrodesis Rod Fixation System
Classification Name:	21 CFR 888.3020 - Intramedullary fixation rod
Product Code:	HSB – Rod, Fixation, Intramedullary and Accessories
Proposed Regulatory Class:	Class II
Sterilizer (Gamma Radiation):	BBF Sterlisationsservice GmbH Willy-Rüsch-Str. 4-10 71394 Kernen-Rommelshausen *Certificates are enclosed in Annex III*

OCT 7 2010

Predicate Device:
OsteoBridge® IDSF Fixation Rod System (K051965)
Femorotibial Medullary Nail Zimmer Inc. (K853250)
Knee Fusion Nail, Smith & Nephew, Inc. (K050938)

Device Description:
OsteoBridge® Intramedullary Knee Arthrodesis Rod Fixation System (IKA) is a series of modular intramedullary rod segments that may be used as either proximal or distal segments. The segments are designed to be attached together to form a complete intramedullary rod using a semicircular hollow angled attachment shell that is clamped together with multiple screws to create a firm fixation of the bone. We strongly recommend covering the attachment shell with bone graft to enhance callus formation.
All components are manufactured from Ti-6Al-4V conforming to ISO 5832-3. The intramedullary rods can be fixed with interlocking screws without or with bone cement.

The device consists of:

Nails with collar: Dia.: 10, 12, 14 and 16 mm in Lengths: 110, 130 and 150 mm
Nails without collar: Dia.: 14, 16 and 18 mm in Lengths: 130, 150 and 200 mm
Attachment Shells: 10° Angled: 50 mm length
Interlocking Screws: Dia. 5 mm in lengths: from 20 mm to 56 mm in two millimeter intervals

Intended use:
Intramedullary knee arthrodesis

Indications include:

1. Irretrievably failed total knee arthroplasty
2. Limb salvage
3. Oncology surgery
4. Any other condition where there is little soft tissue or bony tissue available for support and arthrodesis is the treatment of choice

The intramedullary rods can be fixed with interlocking screws without or with bone cement.

Summary of Technologies:
Similarities
The OsteoBridge® IKA has the same functional characteristics (modular internal rod fixation system) as the predicate device (K051965 / K853250 / K050938) and is made of the same titanium alloy material. The OsteoBridge® IKA has the same intended use as the predicate device (K050938).

Differences
In comparison to the above mentioned predicate device (K051965), the OsteoBridge® IKA System is designed for fusion of the knee joint. Both devices are anchored in the diaphysis of the bone. The performance is therefore comparable.
In comparison to the predicate device (K050938) the OsteoBridge® IKA is a modular system with two nails. In comparison to the predicate device (K853250) the two nails of the OsteoBridge® IKA must be joined using the attachment shell.
The OsteoBridge® IKA provides an angled attachment shell to allow the adjustment of extension/flexion and valgus/varus positioning. The nails are modified to meet the needs of the damage following failed total knee arthroplasty.

Mechanical Testing:
In order to demonstrate that the OsteoBridge® IKA has the mechanical properties necessary to perform its intended use, and that the device performs as well as or better than the predicate device, Merete has conducted mechanical and functional testing. This includes:

- Static Torsion Test
- Four-Point Bending Fatigue Test
- Three-Point Bending Fatigue Test of the IDSF Locking Screws (used also for IKA System)

The tests represent the worst case scenario for the strength of the system. All tests were passed.

The "worst case" was tested.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Merete Medical GmbH
% Mr. Emmanuel Anapliotis
President & CEO
Alt Lankwitz 102
12247 Berlin, Germany

OCT 7 2010

Re: K101939
Trade/Device Name: OsteoBridge IKA Intramedullary Knee Arthrodesis Rod Fixation System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: July 7, 2010
Received: July 12, 2010

Dear Mr. Anapliotis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1. Indications for Use of OsteoBridge® IKA

Indications for Use

510(k) Number (if known): K101939

Device Name: OsteoBridge® IKA Intramedullary Knee Arthrodesis Rod Fixation System

Intended Use:
Intramedullary knee arthrodesis

Indications include:
1. Irretrievably failed total knee arthroplasty
2. Limb salvage
3. Oncology surgery
4. Any other condition where there is little soft tissue or bony tissue available for support and arthrodesis is the treatment of choice

The intramedullary rods can be fixed with interlocking screws without or with bone cement.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101939